



JOHN E. FOGARTY
INTERNATIONAL
CENTER

Advisory Board

Summary Minutes
of Fifty-eighth Meeting

September 14, 2004

U.S. Department
Of Health and
Human Services

National Institutes of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
National Institutes of Health

John E. Fogarty International Center
for Advanced Study in the Health Sciences

Advisory Board
Summary Minutes

Date: September 14, 2004
Place: Lawton Chiles International House
National Institutes of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
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John E. Fogarty International Center
for Advanced Study in the Health Sciences

Minutes of the
Advisory Board

Fifty-eighth Meeting
September 14, 2004

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) convened the fifty-eighth meeting of its Advisory Board on Tuesday, September 14, 2004, at 8:40 a.m., in the Conference Room of the Lawton Chiles International House, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public from 8:40 a.m. to 11:55 a.m., followed by the closed session, from 1:00 p.m. to adjournment at 2:30 p.m., as provided in Sections 552b(c) (4) and 552b(c) (6), Title 5, U.S. Code, and Section 10 (d) of Public Law 92-463, for the review, discussion, and evaluation of grant applications and related information.¹ Dr. Sharon Hrynkow, Acting Director, FIC, presided as chair. The Board roster is appended as Attachment 1.

Board Members Present:

Dr. Wafaie Fawzi
Dr. Douglas C. Heimburger
Dr. Yvonne T. Maddox (*ex officio*)
Dr. Sharon L. Ramey
Dr. Robert R. Redfield
Dr. Stephen E. Straus (*ex officio*)
Dr. May L. Wykle
Dr. Jean A. Wright

Board Members Absent:

Dr. Elizabeth Barrett-Connor
Dr. Patricia M. Danzon
Mr. Dikembe Mutombo
Dr. Lee W. Riley

¹ Members absent themselves from the meeting when the Board discusses applications from their own institutions or when a conflict of interest might occur. The procedure applies only to individual applications discussed, not to *en bloc* actions.

Dr. Burton H. Singer

Members of the Public Present:

Dr. Nelson Sewankambo, Dean, Faculty of Medicine, Makerere University, Uganda

Ms. Shirley Haley, Managing Editor, *Washington Fax*, Washington, D.C.

Ms. Nobayeni Dladla, Health Attaché, Embassy of South Africa, Washington, D.C.

Ms. Mary Woolley, President, Research! America, Alexandria, VA

Federal Employees Present:

Dr. Amar Bhat, OGHA/DHHS

Mr. Kevin Bialy, FIC/NIH

Dr. Joel Breman, FIC/NIH

Dr. Kenneth Bridbord, FIC/NIH

Dr. Bruce Butrum, FIC/NIH

Dr. Ana Chepelinsky, FIC/NIH

Mr. Robert Eiss, FIC/NIH

Dr. Anthony Fauci, NIAID, NIH

Dr. Jean Flagg-Newton, FIC/NIH

Dr. Henry Francis, FIC/NIH

Dr. Pierce Gardner, FIC/NIH

Dr. Dan Gerendasy, CSR/NIH

Dr. Ruth J. Hegyeli, NHLBI/NIH

Dr. Karen Hofman, FIC/NIH

Mr. George Herrfurth, FIC/NIH

Dr. Sharon Hrynkow, FIC/NIH

Mr. Andrew Jones, FIC/NIH

Ms. Patricia Jordan-Williams, FIC/NIH

Dr. Flora Katz, FIC/NIH

Dr. Linda Kupfer, FIC/NIH

Ms. Sonja Madera, FIC/NIH

Ms. Lesley Magnuson, FIC/NIH

Ms. Alisa A. McCullar, FIC/NIH

Dr. Kathy Michels, FIC/NIH

Dr. Mark Miller, FIC/NIH

Mr. Richard Miller, FIC/NIH

Mr. Richard Millstein, FIC/NIH

Ms. Sherri Park, NICHD/NIH

Dr. Aron Primack, FIC/NIH

Ms. Charlotte Quinn, FIC/NIH

Dr. Joshua Rosenthal, FIC/NIH

Ms. Julia Royall, FIC/NIH

Dr. Lone Simonsen, NIAID/NIH

Dr. Barbara Sina, FIC/NIH

Ms. Natalie Tomitch, FIC/NIH

Dr. Sandy Warren, CSR/NIH

Ms. Helen Wegman, NHLBI/NIH
Mr. Randolph Williams, FIC/NIH

CALL TO ORDER

Dr. Sharon Hrynkow called the meeting to order and welcomed everyone. She introduced Dr. Jean Flagg-Newton, who has returned to FIC as Special Assistant, Office of the Director, FIC, and is serving as Acting Executive Secretary of the Advisory Board and Acting Communications Director, FIC. Ms. Irene Edwards, who was Executive Secretary of the Board and Communications Director, FIC, has retired after 17 years of Federal service.

Dr. Hrynkow noted that the terms of the two ex officio members of the Board, Dr. Yvonne Maddox and Dr. Stephen Straus, will expire after the meeting. She presented each with a certificate of appreciation and thanked both for their service to the Center. Two new Board members will join the Board at its next meeting: Dr. Arthur Kleinman, Department of Anthropology, Harvard University, and Dr. William A. Vega, Department of Psychiatry, Robert Wood Johnson Medical School.

Dr. Hrynkow welcomed two special guests: Ms. Nobayeni Dladla, Embassy of South Africa, and Dr. Nelson Sewankambo, Makerere University, Uganda. She also welcomed several staff from NIH and the U.S. Department of Health and Human Services (DHHS): Dr. Amar Bhat, Office of Global Health Affairs, DHHS; Dr. Ruth Hegyeli and Ms. Helen Wegman, National Heart, Lung, and Blood Institute (NHLBI), NIH; and Dr. Sandy Warren, Center for Scientific Review (CSR), NIH.

II. CONSIDERATION OF MINUTES OF PREVIOUS MEETING

The minutes of the Advisory Board meeting of May 18, 2004, were considered and accepted unanimously.

III. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST

The rules and regulations pertaining to conflict of interest were maintained.

IV. FUTURE MEETING DATES

The following meeting dates were confirmed:

Tuesday, February 8, 2005
Tuesday, May 24, 2005
Tuesday, September 13, 2005

Tuesday, February 7, 2006
Tuesday, May 23, 2006
Tuesday, September 12, 2006

All subcommittees of the Board will meet on the Monday preceding each Board meeting.

V. REPORT OF THE DIRECTOR

Dr. Hrynkow reported on major developments in staffing, congressional items, programs and initiatives, and diplomatic activities occurring at the FIC since the May Board meeting. She asked staff to elaborate on selected topics, which included the budget, outreach activities, and program evaluations. The written Report of the Director, which was mailed to Board members, is appended to these minutes as Attachment 2. Additional details on most of the items summarized below are provided in Attachment 2.

Personnel Changes

Dr. Hrynkow reported that FIC has used a new approach to bring staff members to FIC's Division of International Relations (DIR), namely to identify NIH staff members interested in gaining international experience through an assignment at FIC. At the same time, FIC gains insights and experience from the categorical institutes. Dr. Hrynkow introduced two individuals from other NIH components who recently joined FIC as DIR program officers: Dr. Henry "Skip" Francis, from the National Institute on Drug Abuse (NIDA), who is providing leadership for FIC's Sub-Saharan Africa portfolio, and Dr. Ana Chepelinsky, from the National Eye Institute, who is providing leadership for FIC's Latin America and Caribbean portfolio. A third individual, Dr. Zakir Bengali, from the CSR, has responsibility for FIC's South Asia portfolio and is currently in India on behalf of FIC.

Ms. Minerva Rojo, director of DIR, is on detail to the Office of the Director, NIH, to assess policies and practices related to dual-use technologies worldwide. Mr. Richard Millstein, Acting Deputy Director, FIC, served as Acting Director, DIR, in June–August, and Mr. Rob Eiss, Senior Advisor for Strategic Initiatives, FIC, is serving as Acting Director, DIR, in September.

Dr. Richard M. Krause, Senior Scientific Advisor, FIC and National Institute of Allergy and Infectious Diseases (NIAID), has taken on an assignment to lead the newly established Regional Emerging Disease Intervention (REDI) Centre in Singapore until a permanent director is identified. The REDI Centre, a joint activity between the Singapore Ministry of Health and DHHS, will develop training in infectious disease surveillance and foster collaborative research in the region.

FIC Budget

Mr. Richard Miller, Executive Officer, FIC, reported on the status of the FIC budget. The President's Budget for Fiscal Year (FY) 2005 requests approximately \$67.1 million for FIC, an increase of \$1.8 million over the approximately \$65.3 million appropriated in FY 2004. Mr. Miller noted that the Senate Appropriations Committee has not yet acted on the President's Budget request

and that the House Appropriations Committee has provided the same amount as in the President's Budget. The full House is just beginning its appropriations debate. When FY 2005 begins, on October 1, 2004, the NIH expects to be operating on a continuing resolution.

Congressional Items

Dr. Hrynkow noted that Dr. Elias Zerhouni, Director, NIH, has devoted significant attention in the past months to working with Congress on the issue of conflict of interest. This issue is urgent and important for NIH, and policies concerning conflict of interest are evolving. Dr. Hrynkow emphasized that the ongoing discussions affect every NIH Institute and Center (IC).

On June 28, at the invitation of the Rhode Island delegation and Congressman Jim Langevin, in particular, FIC participated in a Capitol Hill briefing on global health. The specific focus of the briefing was the global burden of mental illness and approaches to address the burden through NIH activities. Dr. Hrynkow was joined at the briefing by Dr. Richard Nakamura, Deputy Director, National Institute of Mental Health, Dr. Nora Volkow, Director, NIDA, and an FIC grantee, Dr. Eric Caine, University of Rochester, to give presentations on "The Silent Epidemic of Mental Disorders: The Growing Global Burden." Dr. Hrynkow noted that Senators Chafee and Reed and Congressmen Kennedy and Langevin showed great interest in and support for FIC activities and that the event resulted in requests for FIC information from various other offices on Capitol Hill.

Programs and Initiatives

Delegation to Russia. Dr. Hrynkow represented FIC on Secretary Thompson's delegation to Moscow and St. Petersburg, Russia, in late June. At St. Petersburg State University, the team met with several FIC trainees participating in two FIC programs, the AIDS International Training and Research Program (AITRP) and International Training and Research in Emerging Infectious Disease (ITREID) program. Secretary Thompson announced a \$35 million award from the Global Fund to Fight AIDS, Tuberculosis and Malaria to support efforts against AIDS in Russia, and he gave a major address on medicine and diplomacy.

Fogarty-Ellison Fellowship Program in Global Health and Clinical Research. In July and August, the FIC hosted an 18-day orientation at the NIH for the first class of 31 Fogarty-Ellison fellows. The group, comprised of 20 U.S. students and 11 of 16 foreign counterparts, is participating in 1 year of collaborative, mentored clinical research training at institutions in developing countries. The program, which pairs U.S. and foreign trainees in a "twinning" relationship, is generating much interest and enthusiasm. The orientation consisted of presentations by scientists and international leaders, including U.S. Surgeon General Dr. Richard Carmona and four IC directors; small workshops; and development of mock research grant proposals. FIC and the National Center on Minority Health and Health Disparities (NCMHD) along with the Ellison Foundation co-funded the program in its first year. Other NIH ICs have indicated interest for FY 2005.

Dr. Pierce Gardner, Senior Advisor for Clinical Research and Training, FIC, commented that the orientation was energizing for both fellows and faculty and that one research paper has already emerged. He said that FIC views the fellowships as Rhodes fellowships for young people interested

in global health affairs. FIC will expand the number of doctoral students in the health sciences (e.g., dentistry, nursing) participating in the program. Currently, 19 of the 20 U.S. participants are medical students and 1 is a doctoral student in public health. Several of the medical students are also pursuing doctoral degrees or have master's-level training and/or a degree in public health. FIC is reaching out to health professional schools to encourage students' participation in the program. FIC expects to increase participation to 30 U.S. students and 30 foreign counterparts in FY 2005.

Alumni Associations. Dr. Hrynkow reported that FIC and the National Institute of Environmental Health Sciences (NIEHS) are launching a pilot effort to establish alumni associations of NIH Visiting Fellows and FIC-supported trainees in key countries. The aim is to help young scientists who return home to network, share experiences, and have a supportive framework for their research. The pilot effort will begin in five countries—Brazil, China, India, Mexico, and South Africa. The effort in India will include trainees supported by the Centers for Disease Control and Prevention (CDC). Dr. Hrynkow noted that the selected countries have a critical mass of hundreds of former trainees and that the FIC has good contacts in these countries for tracking the careers of scientists returning home.

Links with Schools of Public Health. Dr. Hrynkow noted that FIC is strengthening links between its research training programs and schools of public health in developing countries. Drawing on the research training expertise that it has built in developing countries, FIC is supporting pilot efforts by FIC grantees to establish schools of public health in, for example, Malawi and, most recently, Russia. Discussions are also under way with groups in the Baltic countries and India. Dr. Kenneth Bridbord, Director, Division of International Training and Research, FIC, noted that FIC has a special opportunity to encourage multiple programs in different areas of public health research to work together for a common goal—forming linkages to facilitate the schools of public health effort. He said that FIC is providing supplemental funds to grantees to support initial grass-roots efforts and that expansion will depend on governments' willingness to contribute.

Outreach

Burden of Malaria. Dr. Joel G. Breman, Senior Scientific Advisor, Division of International Epidemiology and Population Studies (DIEPS), FIC, reported that 37 papers, most of which were presented at the Third Pan-African MIM Conference, held in Arusha, Tanzania, on November 18–22, 2002, have been published as supplement 2 to the *American Journal of Tropical Medicine and Hygiene* (vol. 71, August 2004). The supplement is entitled “The Intolerable Burden of Malaria: II. What’s New, What’s Needed.” Dr. Breman noted that the conference was the largest ever held on malaria and that the papers address the clinical and epidemiological burden of the disease and its economic and social costs. Dr. Breman is one of three guest editors for the supplement. He commented that NIH’s expenditure of \$100 million for research on malaria is increasing rapidly in response to the higher profile given to malaria in recent years.

Program Evaluations

Population and Health. Dr. Linda L. Kupfer, Evaluation Officer, Division of Advanced Studies and Policy Analysis, FIC, reported that an expert panel of five members met for several days at NIH to evaluate the International Research and Training Program in Population and Health program supported by FIC, the National Institute of Aging, and the National Institute of Child Health and Human Development (NICHD). The panel suggested changes in the management and focus of the program, to include emphasis on aging and adult health, population and environment, nutrition, and migration and expansion to Africa and the Middle East for reproductive biology. Dr. Kupfer noted that the review will be helpful as FIC and its partners consider the next competition of the program.

AITRP. Dr. Hrynkow noted that the second phase of FIC's evaluation of the AITRP, its largest training program, will begin in October.

Science for Global Health: Successes

Dr. Hrynkow noted that FIC is making a concerted effort to highlight advances made as a result of its investments. "Scientific success stories" will be included in FIC newsletters and other communication materials. FIC Board member Dr. Wafaie Fawzi reported on one advance.

Multivitamin Supplements and HIV/AIDS. Dr. Fawzi reported the findings of a study conducted in Tanzania, which were published recently in the *New England Journal of Medicine* (vol. 351, pp. 23–32, 2004). In this study, Dr. Fawzi and his colleagues at the Harvard School of Public Health showed that administration of multivitamin supplements containing high doses of vitamin B complex and vitamins C and E to HIV-infected women during pregnancy and for more than 5 years after they gave birth reduced their symptoms of AIDS. Most of the women were asymptomatic at baseline. The supplementation was associated with an approximately 40 percent reduction in risk of fetal death, low birthweight, prematurity; a significant reduction in the progression of HIV disease; a significant increase in CD4+ cell counts; and a reduction in viral load. Dr. Fawzi noted that the 10-year study, which was supported by FIC and NICHD, is the first large clinical trial of outcomes with use of supplements in HIV-infected patients in Sub-Saharan Africa and demonstrates the importance of providing supplements at early stages of HIV disease.

Diplomatic Activities

Health Research in the Middle East. Dr. Hrynkow joined Dr. Zerhouni in productive and positive meetings during the summer with Ministers of Health from Jordan and Iraq. The Iraqi Minister of Health discussed short- and long-term needs in health care and research. NIH is considering ways to work with the Iraqi people to re-energize their medical research infrastructure. FIC will identify training possibilities, including use of Internet-based teaching tools.

Latin America and Caribbean. In June, FIC convened an afternoon session for diplomats from Washington, D.C.-based embassies from the Latin America and Caribbean region. The purpose was to share information on advances in priority health areas and to discuss potential collaborations. Dr. Andrew von Eschenbach, Director, National Cancer Institute (NCI), Dr. Nora

Volkow, Director, NIDA, and Dr. Barbara Alving, Acting Director, NHLBI, spoke about priorities in their institutes, and Dr. Hrynkow discussed FIC and general NIH opportunities, including the Visiting Program. FIC intends to have a similar session this fall for diplomats from the Africa region.

Selected Staff Activities

Dr. Hrynkow referred the Board to the selected activities of FIC staff members described in her written report. She noted that staff undertake a wide breadth and depth of activities, including participation in scientific conferences, in addition to their primary responsibilities. These activities help to keep them abreast of the science in their fields and to maintain and establish new international contacts.

VI. BRINGING GLOBAL HEALTH RESEARCH CLOSER TO HOME: PUBLIC ATTITUDES AND THE IMPORTANCE OF PUBLIC ENGAGEMENT

Ms. Mary Woolley, President, Research! America, described the mission, goals, and activities of Research! America and presented poll data on public attitudes regarding global health. She provided Board members a hard copy of the data she presented and other informational items, which included Research! America's 2003 annual report, fact sheets, and a booklet summarizing other poll data.

Research! America is a nonprofit alliance of more than 475 members broadly representing academia, research institutions, professional and science societies, business and industry, voluntary health organizations, trade associations, foundations and philanthropies, and state and local organizations. Its mission is to "make medical and health research, including research to prevent disease, disability, and injury, a much higher national priority." Research! America has worked with many ICs to make the case for research on programs of NIH and IC interest through compact, publicly attuned messages based on poll data.

Ms. Woolley emphasized the need for quantum leaps in research, and research funding, to help contain the increasing costs of health care. She noted that less than 6¢ of every \$1 spent on health in the United States is spent on medical and health research and that the United States spends much less than 1¢ of every \$1 on medical and health research designed to improve health around the world. Ms. Woolley noted that effective messages to foster public support for this research could, for example, draw comparisons with other U.S. spending habits (e.g., Web shopping, sports activities) or convey the success and promise of research (e.g., on HIV/AIDS). She said that Research! America has used its national, state, and issue-specific polling data collected over more than 12 years to develop successful media products, including 1-pagers replete with sound bytes that can form the basis for short articles inserted into popular magazines (e.g., *PARADE*, *Good Housekeeping*).

Ms. Woolley summarized some of Research! America's poll data which are collected by telephone and/or online. The data indicate that most Americans (91 percent) think it is very or somewhat important for the United States to be a world leader in medical and health research. In

addition, most Americans strongly support basic research and think that clinical research is valuable and that research institutions should work together. Most Americans perceive that preventable diseases and injuries are a major health problem, that too little is spent on prevention research, and that eliminating health disparities is important. Yet, almost 50 percent of Americans do not know of any institutions, companies, or organizations in the United States where medical research is conducted, and 65 percent want more information about medical research.

Global Health Research. Ms. Woolley elaborated on data indicating the public's knowledge and attitudes about global health issues. These data were collected in spring 2004 in a survey commissioned by Research! America with support from the Ellison Foundation. The data indicate that the American public is aware of differences in the leading causes of death in the United States compared with poor or developing countries (for the latter, 70 percent cited malnutrition and famine and 51 percent cited HIV/AIDS as the first and second leading causes of death, respectively). Most of the Americans surveyed (61 percent) said they are somewhat familiar with health problems facing the world and almost one-half said they are concerned about these problems—findings that indicate opportunities for advocacy for global health research. The survey respondents expressed concern about infectious diseases (specifically, HIV/AIDS, influenza, tuberculosis, and Severe Acute Respiratory Syndrome, or SARS) as a first priority, and most of the respondents (81 percent) strongly or somewhat agreed that infectious diseases cannot be contained within national borders and thus are a problem for all countries.

Among the respondents, 35 percent cited medical and health research as a top priority for U.S. Government spending around the world. Disease prevention is a priority for Americans, as evident from the percentage of respondents who cited the following efforts as a somewhat or top priority for U.S. Government spending around the world: education (86 percent), medical and health research (82 percent), training of doctors and health professionals (81 percent), and provision of health care services (70 percent). More than three-fourths of the respondents said that the United States should be involved in improving health around the world because it is a world leader in scientific expertise and medical research; the same proportion noted that improving health will prevent future health crises. The smallest percentage (52 percent) said that improving health would help in the fight against terrorism and political instability.

When asked about U.S. spending for global health research, 71 percent of the respondents said that 1¢ on every \$1 is too little, and 25 percent said that the United States should spend more than 10¢ on every \$1 (19 percent said between 6¢ and 9¢). Ms. Woolley suggested that these findings indicate that the public would support substantial increases in funding for global health research.

Ms. Woolley noted that other survey data complement the findings of the Research! America survey. For example, data collected in the Pew Global Attitudes Project show that AIDS and infectious diseases is a top concern globally (in 17 of 44 countries). Pointedly, the Pew data also show that the perceived greatest threat to the world varies widely—for example, nuclear weapons is cited most often in the United States, whereas infectious diseases/AIDS is cited most often in Africa. The Pew data were collected in interviews of 38,000 individuals in 44 countries and are presented in a report entitled *What the World Thinks in 2002* (The Pew Research Center, December 2002).

What Can Researchers Do? Ms. Woolley emphasized that researchers must be accessible and accountable to the public. They can foster public support of health and medical research by assuming the role of “citizen scientist” and inviting the public to communicate and converse with them about their research. An effective message is: “I work for you.” Researchers could talk with the public about the value of research in improving global health, give examples of research that supports global health, and link their examples to the public’s top concerns. Researchers also could develop alliances with voluntary health organizations, which are skilled in making the case for research and have enormous political power. Researchers must value engagement with the public and find ways to foster and reward researchers who engage the public.

As The Honorable John Edward Porter said, when recently speaking to scientists, “... your voice, your effort, your participation...are essential and vitally needed to influence positively the public policies affecting science.” And, as The Honorable Paul G. Rogers emphasized during FIC’s 35th Anniversary Symposium, “Without research, there is no hope.”

Discussion

Ms. Woolley encouraged the Board members to access poll data and other materials on Research! America’s web-site at www.researchamerica.org. Dr. Hrynkow noted the excellent data and practical wisdom developed by Research! America should be made available to all FIC grantees and trainees. Ms. Woolley noted that accountability is a great concern among the public, and she encouraged all stakeholders in the research enterprise to acknowledge this concern and to communicate examples of researchers’ being accountable to the public. Elaborating on public trust issues, Ms. Woolley highlighted the role of voluntary health organizations in communicating to patients the success and challenges of research and need for the media to inform the public about opportunities to participate in clinical trials and research. Additional data are needed to clarify the reasons for the large difference between the percentage of Americans willing to support clinical research (approximately 65 percent) and the percentage willing to participate in this research (approximately 50 percent). Public participation in clinical research and in decision making on the design and conduct of research must be valued.

VII. EMERGING AND RE-EMERGING INFECTIOUS DISEASES: A PERPETUAL CHALLENGE

Dr. Anthony Fauci, Director, NIAID, broadly discussed the scientific challenges in understanding and preventing the major emerging and re-emerging infectious diseases of the world. In contrast to the U.S. Surgeon General’s testimony before Congress in 1967, Dr. Fauci emphasized that the war against infectious diseases has not been won. Infectious and parasitic diseases are the second leading cause of death worldwide (accounting for 26 percent of all deaths in 2002), following cardiovascular disease (at 29 percent), and are the leading cause of death among young people and the leading cause of morbidity (based on disability-adjusted life years). The two leading infectious diseases as cause of death are acute lower respiratory infections and HIV/AIDS.

Dr. Fauci noted that the model for describing infectious diseases was refined in recent years to include three components: newly emerging diseases (e.g., HIV/AIDS, SARS); re-emerging or resurging diseases (e.g., West Nile Virus); and “deliberately emerging” diseases (e.g., caused by bioterrorism agents such as anthrax). The strategies to confront each threat are similar, and one or more new disease threats emerge each year globally. The delicate balance between microbes and humans, which will always exist, reflects humans’ accidental and deliberate changes (e.g., travel, economic development, public health measures) and microbes’ exceptional natural ability to adapt to change. Microbes have shaped history and civilization—for example, from the first recorded case of smallpox in 1157 B.C. (Pharaoh Ramses V) to the development of a smallpox vaccine in 1796 (by Dr. Edward Jenner).

Dr. Fauci noted that the countermeasures for emerging and re-emerging infectious diseases are threefold—diagnostics, therapeutics, and vaccines—and rely on a broad public health response that includes basic and applied research as a major component. In this early part of the 21st century, the science base incorporates genomics and proteomics; synthetic chemistry, robotics, and drug design; computational and mathematical modeling of molecular and genetic epidemiology; and information technology. Because of spectacular technological advances in recent years, scientists can now sequence a microbe within a day or so, quickly determine the virulence factors, and identify targets for a vaccine.

Dr. Fauci summarized the challenges presented by HIV/AIDS, malaria, tuberculosis (TB), influenza, SARS, West Nile Virus, and bioterrorism agents such as anthrax. He noted that each presents an interesting story.

HIV/AIDS. One of the greatest scourges of history, HIV/AIDS already is responsible for 23 million deaths worldwide. In 2003 alone, the number of new infections approached 5 million and the number of deaths approached 3 million. Two-thirds of the people living with HIV/AIDS (PLWHA) reside in Sub-Saharan Africa, and the next epicenter is likely to be in Asian countries (e.g., China, India) where even a small percentage affected can be tens of millions of people. In the United States, almost 900,000 cases and approximately 500,000 deaths have been reported through 2002, and almost 1 million are PLWHA. The 12-year plateau of new infections continues, one at which approximately 40,000 new cases of HIV are diagnosed each year, with one-half under age 25.

The funding for research on antiretroviral (ARV) treatment has had high payoffs, and the Food and Drug Administration (FDA) has approved more than 20 ARVs—more than for all other viruses combined. Because of the availability of treatments, the number of PLWHA will continue to increase. A major issue globally is the disparity in access to treatments, as highlighted at the 14th International AIDS Conference, in Durban, South Africa, in 2000. While 84 percent of PLWHA in the United States are receiving the drugs they need, only 2 percent of those in Africa are. Dr. Fauci noted that this disparity is rapidly changing, largely because of three collaborative mechanisms: the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria; the President’s Emergency Plan for AIDS Relief (PEPFAR); and bilateral agreements with non-governmental organizations (NGOs).

Dr. Fauci noted the need for a comprehensive strategy of prevention for HIV disease that includes prevention of mother-to-child transmission, education and behavioral modification, and

use of condoms. He also emphasized the importance and difficulty of developing an effective vaccine. Obstacles in this effort are operational, social, and financial, and the most significant factor is the uniqueness of the microbe and scientists' inability to delineate correlates of immunity. To accelerate development of a preventive vaccine, researchers are organizing the virtual Global HIV Vaccine Enterprise, first described in *Science* in June 2003. Dr. Fauci noted that collaboration, cooperation, and transparency are essential in all international health efforts.

Malaria. For decades, malaria has been a major cause of morbidity and mortality globally, with 1.5 million to 2.7 million deaths annually and 300–500 million new infections each year. Every 30 seconds, a child dies from malaria. Dr. Fauci noted that scientists have sequenced the genomes of the three acting partners in malaria: *Plasmodium falciparum*, the major microbial species causing malaria; the vector mosquito; and humans. The challenge now is to use the genomic tools available to translate findings in the functional genomics of malaria to diagnostics, therapeutics, and vaccines.

TB. An estimated one-third of the world's population is infected with TB; a new infection occurs every second; 9 million individuals develop active TB each year; and 300,000 new cases of multidrug-resistant TB arise each year. In 2002 alone, 8 million individuals died of TB. Dr. Fauci noted that, for the first time in 60 years, trials of new candidate vaccines for TB are under way.

Influenza. Influenza is perhaps the most worrisome emerging and re-emerging infection. The annual burden of influenza is very high globally. In the United States alone, approximately 200,000 individuals are hospitalized with influenza each year and 36,000 die from influenza each year. The threat of a major pandemic is ever present and could result in more than 500,000 deaths in the United States, as occurred in the influenza pandemic of 1918–19. The possibilities of a major antigenic shift or a jumping of species (e.g., from birds to humans, as with H5N1) are great concerns. Dr. Fauci noted that companies have not been given adequate incentives to develop products such as vaccines, which have low economic payoffs, and that NIAID is becoming very actively involved in “pushing the envelope” for development of influenza vaccines.

SARS. The combination of epidemiology research and public health measures to identify the microbe responsible for SARS and to control its transmission is an extraordinary success story. This microbe has been held in check since the first year when it emerged and caused 8,000 cases and 800 deaths. Yet, the underlying conditions of human–animal interactions are essentially the same and scientists must remain vigilant and maintain their collaboration, cooperation, and transparency in confronting this disease. Dr. Fauci noted that researchers have created animal models, established correlates of immunity, and developed vaccines that are protective in mice.

West Nile Virus. This virus has appeared in almost every U.S. state since first identified in 1999. In 2004, more than 1,300 U.S. residents were diagnosed with West Nile Virus and 35 individuals died from the disease through September 10. The virus illustrates well the fundamental epidemiology principles of infectious diseases—emerging from a combination of the “right host,” the “right vector,” and the “right conditions” to spread predictably over time and place. Dr. Fauci noted that scientists have used clever approaches to advance toward developing a vaccine against West Nile Virus. They are testing chimeric vaccines in a Phase I clinical trial, with more trials

planned, and have launched a treatment trial involving 60 U.S. sites and use of passive transfusion of antibodies from individuals who have been exposed and have recovered from West Nile Virus.

Bioterrorism Agents—Anthrax. Dr. Fauci noted that the September 11 attack and the subsequent deliberate spread of anthrax in letters mailed in the United States galvanized U.S. attention on the vulnerability of its population to bioterrorism and fostered greater appreciation of naturally occurring emerging and re-emerging infections. The NIAID and other ICs realized an enormous boost in NIH funding (greater than \$1.5 billion each year from FY 2003 to FY 2005) for fundamental basic and applied research on biodefense, and NIAID prepared the NIAID Strategic Plan for Biodefense Research and research agendas for category A agents and for category B and C agents. NIAID has argued that biodefense research and research priorities must span, and must be incorporated into, the full intellectual spectrum of research on emerging and re-emerging infections, from basic to applied and translational research and to product development.

To stimulate research across the spectrum and to expand the physical capabilities for this research, NIH funded eight Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research. Dr. Fauci noted that the research in these centers and in related NIAID and IC programs focuses on the three key countermeasures against infectious diseases: diagnostics, therapeutics, and vaccines. Already, researchers are making significant advances, for example, in developing safe vaccines against smallpox that could be used in all segments of the population and against Ebola Virus and anthrax.

In closing, Dr. Fauci commented that increased funds for biodefense have been a boon for public health. He referred the Board to Dr. Krause's 1981 book, *The Restless Tide: The Persistent Challenge of the Microbial World* (Washington, D.C.: The National Foundation of Infectious Diseases), which made the point, now long understood, that humans and microbes will never be able to completely eliminate each other. To maintain the delicate balance, humans must rely on their wits, scientific capability, and commitment to public health and biomedical research.

Discussion

Dr. Fauci noted that the infusion of funds for biodefense not only is having an impact on research and research training supported by NIH, but also is being used by DHHS to strengthen the public health infrastructure in the United States, including at state and local levels. Dr. Hrynkow thanked Dr. Fauci and NIAID for their past and continuing support of FIC's research and research training programs. She noted that these programs are helping to provide the "bedrock" for many public health infrastructures worldwide. Dr. Fauci noted that FIC is intimately connected with the broad global issue of emerging and re-emerging infectious diseases and that NIH's strategic plan and research agenda for biodefense offer an umbrella and a door for FIC's continued efforts in this area.

In response to questions, Dr. Fauci highlighted the experience with SARS as an excellent model for international collaboration, cooperation, and transparency on global health issues. He noted that chronic diseases are also major global health issues and that NIAID is partnering with other ICs and the World Health Organization to consider possible links between infectious diseases and chronic diseases such as cancer and cardiovascular disease. Dr. Fauci said that NIAID is

enthusiastic about placing his staff in key countries to serve full-time as international representatives “on the ground” (similar to CDC’s in-country representatives). He noted that this action is essential, but will be difficult to accomplish given the current limitations on the NIH budget.

VIII. REVIEW OF APPLICATIONS

Mr. Richard Millstein chaired the remainder of the meeting during which the Research Awards Subcommittee reported on its activities. The FIC Advisory Board reviewed a total of 34 scored competing applications at its September 14 meeting.² The applications were in the following programs:

- 22 applications for the Fogarty International Research Collaboration Award (FIRCA) program, out of a total of 25 applications, for \$881,240;
- 7 applications for the International Research Scientist Development Award (IRSDA) program, out of a total of 10 applications, for \$812,684;
- 4 applications for the International Studies on Health and Economic Development (ISHED) program, out of a total of 4 applications, for \$2,677,966;
- 1 NIH Roadmap-related application, out of 1 application transferred from NCI for a total of \$37,541.

The Board concurred with the initial review group recommendations for 33 out of 34 applications.

IX. ADJOURNMENT

There being no further business, the meeting was adjourned at 2:30 p.m. on September 14, 2004.

² Applications that were noncompetitive, unscored, or not recommended for further consideration by initial review groups were not considered by the Council.

CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Sharon Hrynkow, Ph.D.
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Center Advisory Board, and
Acting Director,
Fogarty International Center

Jean Flagg-Newton, Ph.D.
Acting Executive Secretary, Fogarty
International Center Advisory Board, and
Acting Communications Director,
Fogarty International Center

ATTACHMENT

1 - Board Roster

Abbreviations Used in the Minutes

AIDS	-	Acquired Immunodeficiency Syndrome
AITRP	-	AIDS International Training and Research Program
ARV	-	Antiretroviral
CDC	-	Centers for Disease Control and Prevention
CSR	-	Center for Scientific Review
DHHS	-	U.S. Department of Health and Human Services
DIEPS	-	Division of International Epidemiology and Population Studies
DIR	-	Division of International Relations
FDA	-	Food and Drug Administration
FIC	-	John E. Fogarty International Center for Advanced Study in the Health Sciences
FIRCA	-	Fogarty International Research Collaboration Award
FY	-	Fiscal year
HIV	-	Human immunodeficiency virus
ICs	-	Institutes and Centers
IRSDA	-	International Research Scientist Development Award
ISHED	-	International Studies on Health and Economic Development
ITREID	-	International Training and Research in Emerging Infectious Disease
NCI	-	National Cancer Institute
NCMHD	-	National Center on Minority Health and Health Disparities
NGOs	-	Nongovernmental organizations
NHLBI	-	National Heart, Lung, and Blood Institute
NIAID	-	National Institute of Allergy and Infectious Diseases
NICHD	-	National Institute of Child Health and Human Development
NIDA	-	National Institute on Drug Abuse
NIEHS	-	National Institute of Environmental Health Sciences
NIH	-	National Institutes of Health
OGHA	-	Office of Global Health Affairs
PEPFAR	-	President's Emergency Plan for AIDS Relief
PLWHA	-	People living with HIV/AIDS
REDI	-	Regional Emerging Disease Intervention (Centre)
SARS	-	Severe Acute Respiratory Syndrome
TB	-	Tuberculosis

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